DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M4295n

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express

Our Reference: 2952561

November 21, 2000

Mr. Anthony W. DeGroot, Owner
Tony DeGroot Dairy
3012 Grangeville Boulevard
Hanford, California 93230

WARNING LETTER

Dear Mr. DeGroot:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on October 24 and 26, 2000, by Food and Drug Administration (FDA) Investigator John A. Gonzalez have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On August 17, 2000, you consigned a calf (identified by USDA laboratory report number 391882) to be slaughtered for human food. This calf was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this calf revealed the presence of sulfamethoxazole in the muscle at 0.43 parts per million (ppm), and in the liver at 0.40 ppm. Presently, there is no tolerance for sulfamethoxazole in the uncooked edible tissues of cattle.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring that drugs are used in a manner consistent with the directions contained in their labeling.

4. You lack an adequate system for assuring that animals have been treated only with drugs which have been approved for use in their species or class.

5. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

The drug Mutual Pharmaceutical brand of Sulfamethoxazole and Trimethoprim tablets that you use to treat your calves is adulterated under Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of Section 201(v), and is unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with approved labeling. Your veterinarian prescribed the Sulfamethoxazole and Trimethoprim tablets for the treatment of scouring in calves. The prescription label warns against releasing animals for slaughter for food within thirty-five days of use. Failure to adhere to your veterinarian's prescribed withdrawal time is likely the cause of the illegal residues found in the animal you sold for food use.

Failure to adhere to labeling directions presents the likely possibility that illegal residues will occur and makes the drug unsafe for use. We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues. You have failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale at an auction where it was held

for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Your firm has established a history of offering animals for sale for human food use, which have been found to be adulterated with drug residues. According to USDA analytical reports, during the period of February 16, 1993, through August 5, 1999, your firm sold [redacted] cows and one calf, which were found to contain illegal residues of oxytetracycline, penicillin and sulfamethoxazole. Also, USDA sent you a letter for each instance in which their analysis found violative levels of drug residues. Inspections were conducted by the state of California and by FDA on April 1, 1993; on February 2, 1996; and on October 25, 1999. During the inspections you were warned that it is illegal to market animals with illegal levels of antibiotics. A Warning Letter, dated March 8, 1996, was sent to you as a result of the violations found during the initial FDA inspection.

Within fifteen (15) days of the receipt of this letter, please notify our office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Russell A. Campbell, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely yours,

Roger L. Lowell
Acting District Director
San Francisco District

cc: [redacted]